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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/801,469

03/16/2004

Jennifer X. Qiao

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07/20/2006

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EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,469

Applicant(s)

QIAO ET AL.

Examiner

Robert Shiao, Ph. D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/27/04, 9/07/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the provisional applications:
60/455,733 with a filing date 03/18/2003; and
60/508,232 with a filing date 10/02/2003.
2. The applicant's petition filed under 37 CFR 1.48(a) and an oath or declaration, dated 03/30/2005, for correction of inventorship for the instant application, is acknowledged. The inventorship has been corrected, and the inventors are:
Jennifer X. Qiao, Tammy C. Wang, Gren Z. Wang and Timur Gungor.
3. Claims 1-14 are pending in the application.

Information Disclosure Statement

4. Applicant's Information Disclosure Statements, filed on May 27, 2004 and September 07, 2004, have been considered. Please refer to Applicant's copies of the 1449's submitted herein.

Responses to Election/Restriction

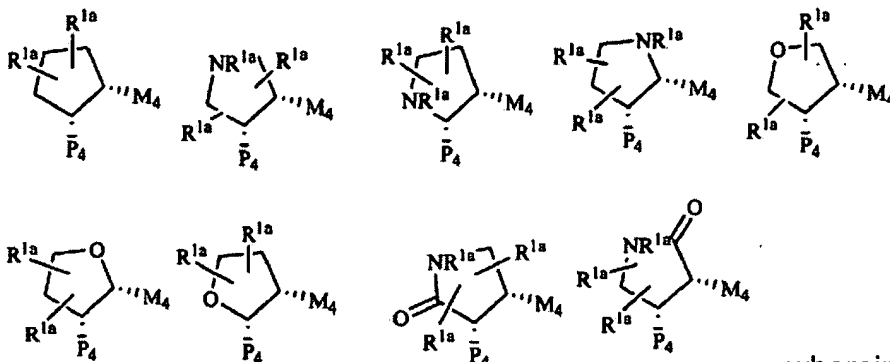
5. Applicant's election of Examples 1, 87 and 97 in the reply filed on May 15, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Art Unit: 1626

Claims 1-10, in part, drawn to a compound/compositions of the formulae,

i.e.,



, wherein one of the variable P4

or M4 is -Z-A-B and the other is -G1-G, the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl, and the variable E ring is not substituted with a heterocycle; the variable G1 does not represent heteroaryl or heterocycle; the variable Z does not represent a heteroaryl or heterocycle, i.e., NR^3R^{3a} does not form ring having an additional heteroatom; the variable A does not represent a heterocycle ring; the variable A is not substituted with a heterocycle; the variable B represents 2H-pyridinyl or piperidine thereof, the variable R^{1a} together with the atoms which they are attached they do not form a 5-7 membered ring having any heteroatom thereof, the variable R^{1a} , R^{1b} , R^{1d} , R^2 , R^{2b} , R^{2c} , R^3 , R^{3a} , R^{3b} , R^{3c} , R^{3d} , R^{3e} , R^{3f} , R^4 , R^{4a} , R^{4b} , R^{4c} , R^5 , R^{5a} , R^6 , R^7 , R^8 , or R^9 independently does not represent heteroaryl or heterocycle thereof, or the variable R^{1a} , R^{1b} , R^{1d} , R^2 , R^{2b} , R^{2c} , R^3 , R^{3a} , R^{3b} ,

Art Unit: 1626

R^{3c}, R^{3d}, R^{3e}, R^{3f}, R⁴, R^{4a}, R^{4b}, R^{4c}, R⁵, R^{5a}, R⁶, R⁷, R⁸, or R⁹ is not substituted with a heterocycle or heteroaryl thereof.

Claims 1-10, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-10, in part, not embraced in above elected subject matter, and claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9, line 2, recites the limitation "Examples 128-429 of Table 1". The limitation fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must stand alone to define invention, and incorporation into claims by express reference to specification is not permitted.

Therefore, the rejection is proper under 35 U.S.C. 112, second paragraph, see *Ex parte Fressola*, No. 93-0828. In order to obviate the rejection, the compound names of Examples 128-429 of Table 1 must be inserted into the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

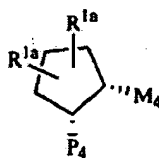
A person shall be entitled to a patent unless –

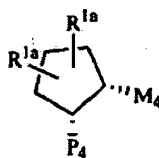
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Pinto et al. US 6,967,208. Pinto et al. '208 is 102(e) reference.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.



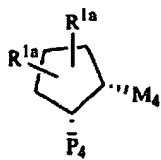
Applicants claim a compound of formula, i.e., , wherein one of the variable P4 or M4 is -Z-A-B and the other is -G1-G, the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof,

Art Unit: 1626

the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl, and the variable E ring is not substituted with a heterocycle; the variable G1 does not represent heteroaryl or heterocycle; the variable Z does not represent a heteroaryl or heterocycle. Dependent claims 2-10 further limit a number of variables, i.e., the variable G1 is NHCO or NHC(=O)CONH.

Pinto et al. disclose eight compounds, i.e., 5-chloro-N-(2-[[4-(2-oxopiperidin-1-yl)benzoyl]amino]cyclopentyl)thiophene-2-carboxamide; 5-chloro-N-(2-[[4-(2-oxopyridin-1(2H)-yl)benzoyl]amino]cyclopentyl)thiophene-2-carboxamide; 6-chloro-N-(2-[[4-(2-oxopyridin-1(2H)-yl)benzoyl]amino]cyclopentyl)-2-naphthamide; 6-chloro-N-(2-[[4-(2-oxopiperidin-1-yl)benzoyl]amino]cyclopentyl)-2-naphthamide; 2-chloro-N-(2-[[4-(2-oxopiperidin-1-yl)benzoyl]amino]cyclopentyl)quinoline-6-carboxamide; 5-methoxy-N-(2-[[4-(2-oxopyridin-1(2H)-yl)benzoyl]amino]cyclopentyl)thiophene-2-carboxamide; 4-methoxy-N-(2-[[4-(2-oxopyridin-1(2H)-yl)benzoyl]amino]cyclopentyl)benzamide; and 4-methoxy-N-(2-[[4-(2-oxopiperidin-1-yl)benzoyl]amino]cyclopentyl)benzamide, see column 109, lines 30-33, and lines 64-65; or column 110, lines 14-15; or column 111, lines 1-2, or lines 16-19.

Pinto et al. compounds clearly anticipate the instant compounds of formula



, wherein the variable R^{1a} represents hydrogen; the one of the variable P₄ or M₄ is -Z-A-B and the other is -G1-G, the variable G1 represents

Art Unit: 1626

$(CR^3R^{3a})_uNR^{3b}C(O)(CR^3R^{3a})_w$ and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen (i.e., $G1$ is $NHCO$); the variable G represents a formula (IIa) or (IIb), and wherein the variable D ring of formula (IIa) or (IIb) is absent and the variable E ring of formula (IIa) or (IIb) represents phenyl substituted with R (i.e., R is OCH_3) or thienyl substituted with R (i.e., R is OCH_3 or Cl); or wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof (i.e., phenyl) and the variable E represents phenyl (i.e., the formula (IIa) or (IIb) represent naphthalene substituted with R , and R represents Cl); or wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof (i.e., phenyl) and the variable E represents pyridyl substituted with R , and R represents Cl ; the variable Z represents $(CR^3R^{3a})_uNR^{3b}C(O)(CR^3R^{3a})_w$ and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen (i.e., Z is $NHCO$); the variable A represents C_{3-10} carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine. Pinto et al. compounds also read on the species of claim 8, i.e., first, second or fourth compound of claim 8. Dependent claims 2-10 of claim 1 are also rejected along with claim 1 under 35 U.S.C. 102(a) or 102(e).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

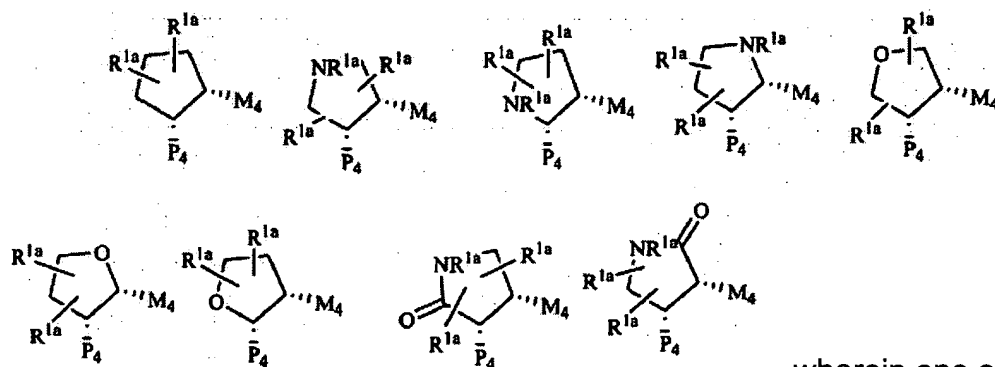
9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being obvious over Pinto et al. US 6,967,208 or US 6,989,391. The applied references have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any

Art Unit: 1626

invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Applicants claim a compound/compositions of the formulae,

i.e.,



, wherein one of the variable P₄

or M₄ is -Z-A-B and the other is -G₁-G, the variable G₁ represents (CR³R^{3a})_uNR^{3b}-C(O)(CR³R^{3a})_w and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms

Art Unit: 1626

thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 further limit a number of variables, i.e., the variable G1 is NHCO or NHCOCONH.

Determination of the scope and content of the prior art (MPEP §2141.01)

Pinto et al. '208 or '391 disclose a compound/compositions of formula (I), i.e., P₄-P-M-M₄, wherein the variable M is a 3-10 membered carbocycle or a 4-10 membered heterocycle, consisting of: carbon atoms and 1-3 heteroatoms selected from O, S(O)_p, or N, and the variable p is 0; the variable P is absent; one of the variable P₄ or M₄ represents -Z-A-B and the other -G1-G, and the variable G represents a formula (IIa) or (IIb), see columns 6-12 of Pinto et al. '208 or '391 .

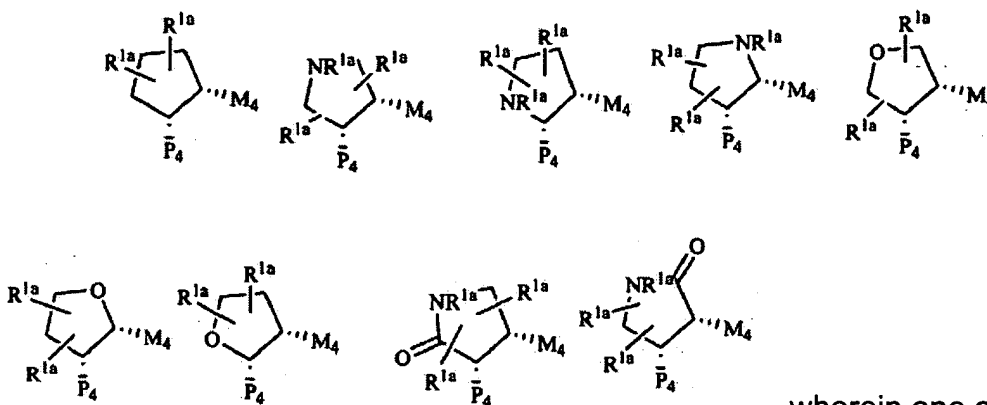
Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between instant claims and Pinto et al. is that the variable P of formula (I) of Pinto et al. is absent or represents a fused 5-7 membered carbocycle ring to variable M, while the instant claims is absent at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

Art Unit: 1626

One having ordinary skill in the art would find the claims 1-10 *prima facie* obvious because one would be motivated to employ the compounds/compositions of Pinto et al. to obtain instant claimed compounds/compositions of formula,



, wherein one of the variable P₄

or M₄ is -Z-A-B and the other is -G₁-G, the variable G₁ represents (CR³R^{3a})_uNR^{3b}C(O)(CR³R^{3a})_w and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 are also rejected along with claim 1 under 35 U.S.C. 103(a) as the same reasons above.

The motivation to make the claimed products derives from the expectation that the instant claimed compounds/liposome derived from known Pinto et al. compounds/compositions would possess similar activities (i.e., treating thromboembolic

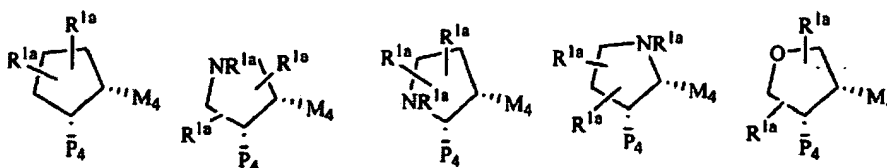
Art Unit: 1626

disorders) to that which is claimed in the reference.

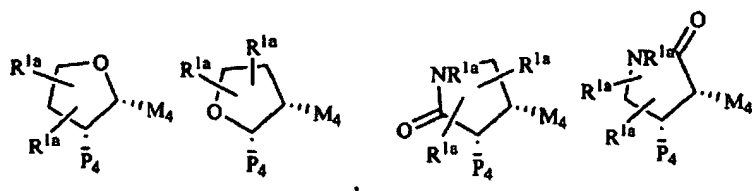
10. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobson et al. US 6,951,872. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicants claim a compound/compositions of the formulae,

i.e., ,



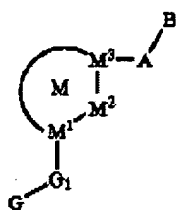
Art Unit: 1626

, wherein one of the variable P₄

or M₄ is -Z-A-B and the other is -G₁-G, the variable G₁ represents (CR³R^{3a})_uNR^{3b} C(O)(CR³R^{3a})_w and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 further limit a number of variables, i.e., the variable G₁ is NHCO or NHCOCONH.

Determination of the scope and content of the prior art (MPEP §2141.01)

Jacobson et al. disclose a compound/compositions of formula (I), i.e.,



, wherein the variable M including M¹, M² or M³ is a 5-7

membered non-aromatic carbocycle or a 5-7 membered non-aromatic heterocycle, consisting of: carbon atoms, 0-3 N and 0-1 heteroatoms selected from O, S(O)_p, and

Art Unit: 1626

the variable p is 0; provided that ring M consist of a total 0-3 O, S(O)p and N; and the variable G1 represents $(CR^{3a}R^{3b})_uNR^3C(O)(CR^{3a}R^{3b})_w$ and variable u and w independently is 0 and the variable R^3 is hydrogen; the variable G represents a formula (IIa) or (IIb); see columns 6-12.

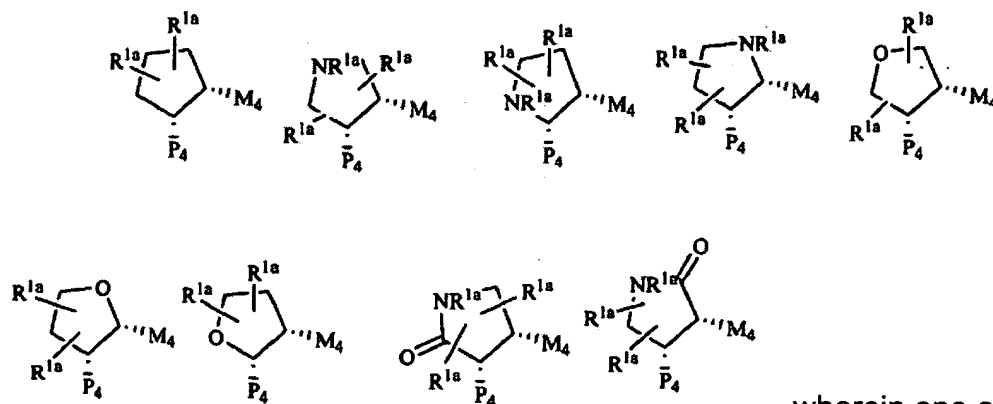
Determination of the difference between the prior art and the claims (MPEP

§2141.02)

The difference between instant claims and Jacobson et al. is that the variable M of formula (I) of Jacobson et al. represents a 5-7 membered non-aromatic carbocycle (i.e., cyclopentyl or cyclohexyl), while the instant claims represents cyclopentyl at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 1-10 prima facie obvious because one would be motivated to employ the compounds/compositions of Jacobson et al. to obtain instant claimed compounds/compositions of formula,



, wherein one of the variable P_4

Art Unit: 1626

or M4 is -Z-A-B and the other is -G1-G, the variable G1 represents $(CR^3R^{3a})_uNR^{3b}$ $C(O)(CR^3R^{3a})_w$ and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C_{3-10} carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 are also rejected along with claim 1 under 35 U.S.C. 103(a) as the same reasons above.

The motivation to make the claimed products derives from the expectation that the instant claimed compounds/liposome derived from known Jacobson et al. compounds/compositions would possess similar activities (i.e., treating thromboembolic disorders) to that which is claimed in the reference.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

Art Unit: 1626

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

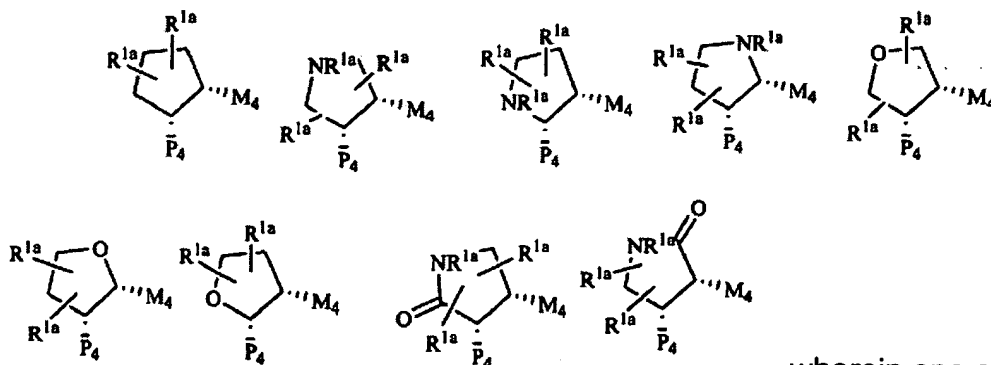
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of Pinto et al. co-pending Application No. 11/198,801, also see US 2005/0267097 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a compound/compositions of the formulae,

i.e., ,



, wherein one of the variable P4

Art Unit: 1626

or M₄ is -Z-A-B and the other is -G₁-G, the variable G₁ represents (CR³R^{3a})_uNR^{3b}C(O)(CR³R^{3a})_w and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 further limit a number of variables, i.e., the variable G₁ is NHCO or NHC(=O)CONH.

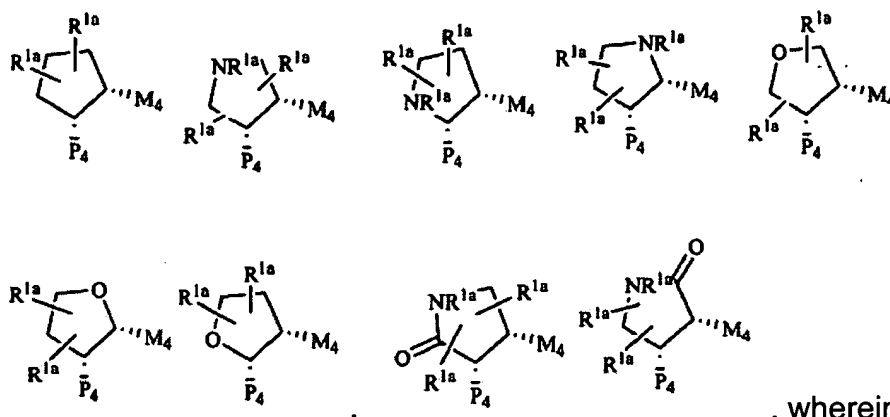
Pinto et al. '801 claim a compound/compositions of formula (I), i.e., P₄-P-M-M₄, wherein the variable M is a 3-10 membered carbocycle or a 4-10 membered heterocycle, consisting of: carbon atoms and 1-3 heteroatoms selected from O, S(O)_p, or N, and the variable p is 0; the variable P is absent; one of the variable P₄ or M₄ represents -Z-A-B and the other -G₁-G, and the variable G represents a formula (IIa) or (IIb), see columns 3-6.

The difference between instant claims and Pinto et al. is that the variable P of formula (I) of Pinto et al. is absent or represents a fused 5-7 membered carbocycle ring to variable M, while the instant claims is absent at the same position.

One having ordinary skill in the art would find the claims 1-10 prima facie obvious because one would be motivated to employ the compounds/compositions of Pinto et al.

Art Unit: 1626

to obtain instant claimed compounds/compositions of formula,



, wherein one of the variable P₄

or M₄ is -Z-A-B and the other is -G₁-G, the variable G₁ represents (CR³R^{3a})_uNR^{3b} C(O)(CR³R^{3a})_w and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 are also rejected along with claim 1 under obviousness-type double patenting as the reasons above.

The motivation to make the claimed products derives from the expectation that the instant claimed compounds/liposome derived from known Pinto et al. compounds/compositions would possess similar activities (i.e., treating thromboembolic disorders) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the

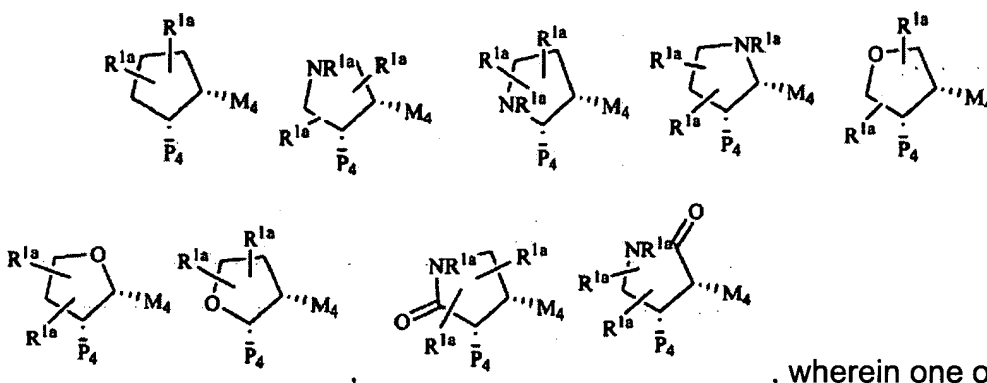
Art Unit: 1626

conflicting claims have not in fact been patented.

13. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 9 of Shi et al. co-pending Application No. 10/952,204, see US 2005/0119266 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a compound/compositions of the formulae,

i.e., ,



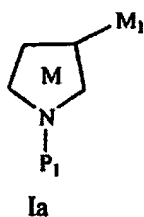
, wherein one of the variable P4

or M4 is -Z-A-B and the other is -G1-G, the variable G1 represents $(CR^3R^{3a})_uNR^{3b}C(O)$ $(CR^3R^{3a})_w$ and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine

Art Unit: 1626

thereof. Dependent claims 2-10 further limit a number of variables, i.e., the variable G1 is NHCO or NHCOCONH.

Shi et al. disclose a compound/compositions of formula (Ia), i.e.,



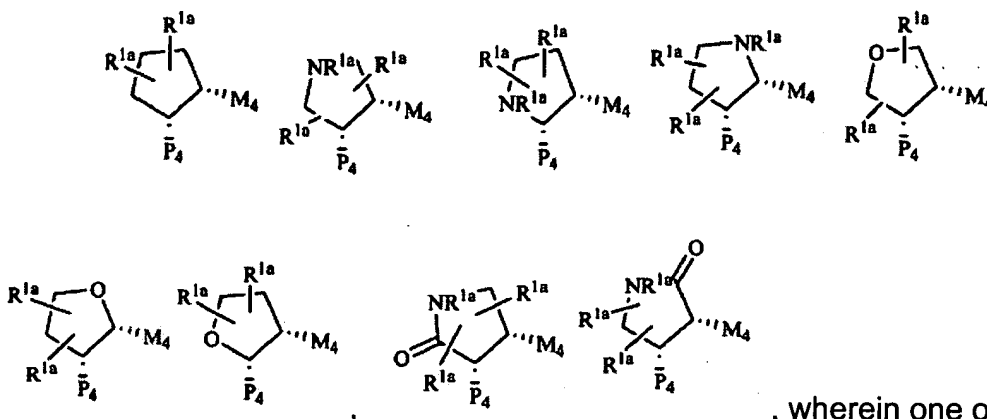
, wherein one of the variable P1 and M1 is -Z-A-B and the other -G1-G; and the variable G1 represents 2-6 membered linear chain consisting of 0 carbon, one carbonyl group, and one herteroatom selected N, and G1 is substituted with one R³ and R³ is hydrogen (i.e., G1 is NHCO); the variable G represents a formula (IIa) or (IIb); the variable Z represents (CR³R^{3e})_qNR^{3b}C(O)(CR³R^{3e})_{q1} and variable q and q1 independently is 0 and the variable R^{3b} is hydrogen; the variable A represents C₃₋₁₀crabocycle (i.e., phenyl); the variable B represents (CH₂)₀₋₂NR²R^{2a} and the variable NR²R^{2a} form a 6 membered saturated or unsaturated ring and consisting of one additional heteroatom selected from N, i.e., (CH₂)₀₋₂NR²R^{2a} form a pyridyl or piperidine ring, see columns 1-5.

The difference between instant claims and Shi et al. is that the variable M of formula (Ia) of Shi et al. represents pyrrolidine, while the instant claims represents pyrrolidine or cyclopentyl at the same position.

One having ordinary skill in the art would find the claims 1-10 prima facie obvious because one would be motivated to employ the compounds/compositions

Art Unit: 1626

of Shi et al. to obtain instant claimed compounds/compositions of formula,



, wherein one of the variable P₄ or M₄ is -Z-A-B and the other is -G₁-G, the variable G₁ represents (CR³R^{3a})_uNR^{3b} C(O)(CR³R^{3a})_w and the variable u or w independently represent 0 and the variable R^{3b} represents hydrogen; the variable G represents a formula (IIa) or (IIb), wherein the variable D of formula (IIa) or (IIb) is a 5-6 membered ring consisting of carbon atoms thereof and not substituted with a heterocycle thereof, the variable E of formula (IIa) or (IIb) is selected from phenyl or pyridyl thereof; or wherein the variable D ring is absent and the variable E ring represents phenyl, thienyl or pyrrolyl; the variable A represents C₃₋₁₀ carbocycle (i.e., phenyl); the variable B represents 2H-pyridinyl or piperidine thereof. Dependent claims 2-10 are also rejected along with claim 1 under obviousness-type double patenting as the reasons above.

The motivation to make the claimed products derives from the expectation that the instant claimed compounds/liposome derived from known Shi et al. compounds/compositions would possess similar activities (i.e., treating thromboembolic disorders) to that which is claimed in the reference.

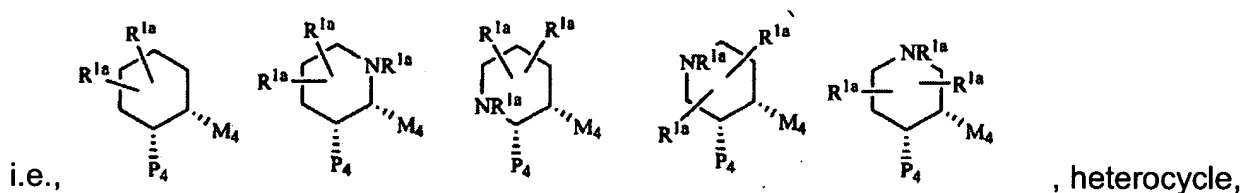
This is a provisional obviousness-type double patenting rejection because the

Art Unit: 1626

conflicting claims have not in fact been patented.

Claim Objections

14. Claims 1-10 are objected to as containing non-elected subject matter,



heteroary, indole, pyrimidine, morpholine, triazole, 1H-benzo[d][1,2] oxazine, quanozoline, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

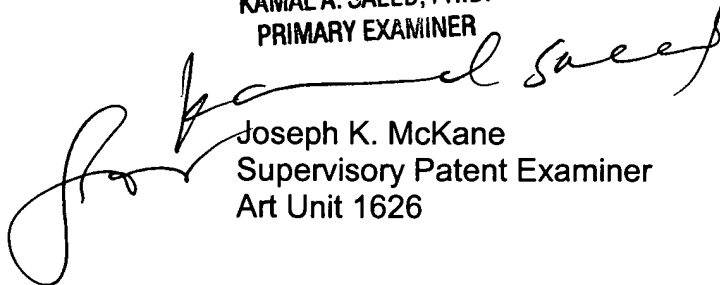
Art Unit: 1626

for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Joseph K. McKane', is written over the printed name and title of the Supervisory Patent Examiner.

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

July 07, 2006